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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,865	01/15/2004	Gary Lim	5010-080-01	5962

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EXAMINER

MENON, KRISHNAN S

ART UNIT PAPER NUMBER

1723

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/757,865

Applicant(s)

LIM ET AL.

Examiner

Krishnan S. Menon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-54 are pending as amended 7/6/06.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-4, 11, 14, 16-29 and 38-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Limb (US 4,832,842) in view of Aysta et al (US 5,620,663); or alternately, Aysta in view of Limb.

Limb teaches a device and a method of filtering, the device having filter body (66) filter connectors (70 and 78), removable vacuum adapter plate (24) having holes, plate connectors (53), connectable collection vessel (18), syringe body (52), conical drip director, all connections are leak-proof, vacuum source, locking devices, etc. (see figures)

The claims differ from the teaching of the reference in the RNA capturing membrane. However, RNA capturing membrane is intended use. Aysta teaches such a membrane capable of RNA capture. Aysta teaches the membrane for nucleic acids, but RNA would behave similarly because it is a nucleic acid, and RNA capture is inherent. Under the principles of inherency, if a prior art device, in its normal and usual

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operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986). The process is taught in column 4 line 59 – column 5 line 29, including chromatographic and eluting steps.

It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Aysta in the teaching of Limb to have the limb system for nucleic acid and similar applications as taught by Aysta.

Aysta teaches a method of filtering and a purification device having a filter (28) with filter connectors to capture nucleic acids, etc., a removable vacuum adapter plate (manifold) having a substrate and a plurality of holes for accommodating the first plate connectors, a connectible collection vessel, first and second filters, conical drip director, glass and polyethylene fibers with pore sizes in the range claimed – see figures, abstract, column 2 lines 27-51, column 3 lines 23-34, column 4 lines 59-64, column 5 line 34 – column 6 line 4, and column 8 line 30 – column 9 line 37. Capturing RNA is an intended use. Blood treatment components or reagents – see abstract and column 2 lines 10-67 and examples. Aysta also teaches a purification system with vacuum source, manifold, seal (inherent), locking devices, plugs for unused holes, centrifuge, etc.

With respect to the process claims 38-47, the reference does not specifically state capturing RNA, but does teach nucleic acids; and RNA is a nucleic acid. In re

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King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986). The process is taught in column 4 line 59 – column 5 line 29, including chromatographic and eluting steps.

Claims differ from Aysta reference in the “plate connectors”, which is taught by Limb as shown above. It would also be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Limb in the teaching of Aysta to have an improved vacuum filtration system as taught by Limb and for continuous operation (see column 3 lines 15-30).

Claim 42 differs from the teaching of the references in “drying” the membrane before eluting the RNA. However, the applicant’s disclosure only describes “drying” as ‘running the vacuum’ to dry the filter, which is inherent or implied in the teaching of the reference, since the reference also teaches using a vacuum to extract the liquid from the samples. “[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” In re Preda, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA 1976).

2. Claims 1,2,4-17,19,20,26-37, 48,49,51, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US 5,989,431).

Evans teaches a purification device, and method of purifying, having a filter (5) with filter connector (4) to capture DNA, a first plate connector (23), a vacuum adapter plate (manifold (31)) having a substrate and a plurality of holes for accommodating the

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plate connectors, a collection vessel (36) – see figures 1-4, abstract and column 7 line 63 – column 8 line 50. Capturing RNA is an intended use, and is also inherent. Blood treatment components or reagents – see abstract and column 2 lines 10-67 and examples. First and second filters – hollow fiber and glass fiber membrane – see figure 1. Syringe body – see example 4 (Also, syringe body only describes a shape – and the body has such a shape in figure 1). Evans also teaches a purification system with vacuum source, manifold (tray with cover), seal (inherent), plugs for unused holes, etc, and a kit as claimed. See column 7 lines 4-44 and examples.

Claims differ from the teaching of Evans in the vacuum adapter being removable. However, being integral (as taught by Evans) or separable (as claimed) would not be a patentable difference. making integral (one piece) or separable (two-part) would be a matter of obvious engineering choice (*In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 CCPA 1965); *In re Dulberg*, 289 F.2d 522,523, 129 USPQ 348,349 (CCPA 1961)).

Response to Arguments

Applicant's arguments filed 7/6/06 have been fully considered but they are not persuasive.

Evans reference: applicant's arguments that Evans does not teach the first plate connectors is not correct. The connectors are identified in the rejection. Arguments regarding the RNA-filter: RNA filter is intended use – the filter of the reference is capable of capturing RNA as shown. Claim 37 recites a syringe body; the part (21) of the reference is like a syringe body. Rest of the arguments are repetitions.

Aysta reference: the cited lines of column 3, lines 12-20 teaches about the provision of generating vacuum in the individual collection container (32) for suction from the sample container. However, this vacuum suction is provided within the chamber (44) and would not cause leakage of the process fluids. Rest of the arguments are moot – new grounds for rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Krishnan S Menon
Examiner
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